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verified the applicant's claim that NDA 19-915 was approved on May 16, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 11, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 8, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 6, 1991.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 91-19118 Filed 8-8-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91E-0224]

Determination of Regulatory Review Period for Purposes of Patent Extension; Orcolon®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Orcolon® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 158(g)(3)(B).

FDA recently approved for marketing the medical device Orcolon®. Orcolon® is indicated for use as a surgical aid in anterior segment surgery, including cataract extraction and intraocular lens implantation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Orcolon® (U.S. Patent No. Re. 32,969) from Seymour F. Trager and Victoria S. Chylinski. The Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 2, 1991, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Orcolon® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Orcolon® is 1,551 days. Of this time, 1,141 days occurred during the testing phase of the regulatory review period, while 410 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: December 31, 1986. The applicant claims October 13, 1986, as the date the investigational device exemption (IDE) became effective. However, FDA records indicate that the IDE was conditionally approved on December 31, 1986.

2. The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: February 13, 1990. The applicant claims July 29, 1987, as the date the premarket approval application (PMA) for Orcolon® (PMA No. P870044) was submitted. However, FDA records indicate that PMA No. P870044 was declared not fileable three times by FDA before being withdrawn by the applicant on June 27, 1988. A second application (PMA No. P900010) was submitted on February 13, 1990 and was accepted by FDA.

3. The date the application was approved: March 29, 1991. FDA has verified the applicant's claim that PMA No. P900010 was approved by FDA on March 29, 1991.

The determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension In its application for patent extension, this applicant seeks 888 days of patent term extension.

Anyone with knowledge that any of the dates are published is incorrect may, on or before October 11, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 8, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1991.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 91-19119 Filed 8-9-91; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting, National Diabetes Advisory Board

Pursuant to Public Law 92-463, notice is hereby given of the National Diabetes Advisory Board's meeting date which will be September 22-24, 1991. The Advisory Board meeting will be in conjunction with the Technical Advisory Committee. The meeting will begin at 7 p.m. on September 22, 1991, and recess at 9:30 p.m. The meeting will reconvene at 8 a.m. on September 23, 1991, and recess at 4:30 p.m. The meeting will reconvene at 8 a.m. on September 24, 1991, and adjourn approximately 4:30 p.m. The Board will meet at the Center for Disease Control, Atlanta, Georgia. The purpose of the meeting is to sponsor a workshop on Diabetes Translation from 1 p.m. to 5 p.m. on September 23, 1991 and from 8 a.m. to noon on September 24, 1991. The Board's current and future activities will be discussed from 1:15 p.m. until approximately 4:30 p.m. on September 24, 1991. Although the entire meeting will be open to the public, attendance will be limited to space available.

For any further information, please contact Mr. Raymond M. Kuehne, Executive Director, National Diabetes Advisory Board, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852, (301) 496-6045. His office will provide, for example, a membership roster of the Board and an agenda and summaries of the actual meetings.

Dated: July 29, 1991.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 91-19012 Filed 8-9-91; 8:45 am]

BILLING CODE 4140-01-M

Consensus Development Conference on The Treatment of Panic Disorder

Notice is hereby given of the NIH Consensus Development Conference on "The Treatment of Panic Disorder," which will be held September 25-27, 1991 in the Masur Auditorium of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. This conference is sponsored by the National Institute of Mental Health and the NIH Office of Medical Applications of Research.

Panic disorder with and without agoraphobia is a debilitating disorder that may afflict as many as 12 million people in the course of a lifetime. It is characterized by panic attacks, which are bursts of terror that seem to come out of the blue. People suffering from a panic attack often feel like they are having a heart attack, or, alternatively, like they are losing their minds. Panic sufferers often develop agoraphobia secondary to the occurrence of these unexpected panic attacks, and they begin to avoid places where they fear a panic attack may reoccur. If the agoraphobia becomes severe enough, a person may become housebound.

In recent years, a gathering body of research information indicates that selected psychopharmacological and psychosocial treatments are effective with panic disorder with or without a history of agoraphobia. Much controversy has surfaced with respect to the nature of, as well as the most efficacious treatment for, panic disorder.

The conference will bring together experts from both the psychological and psychopharmacological camps and other health care professionals as well as representatives of the public to explore the data and evaluate the treatment technology for panic disorder.

Following a day and half of presentations by experts and discussion by the audience, an independent non-Federal consensus panel will weigh the scientific evidence and write a draft statement in response to the following questions:

- What is the diagnosis, epidemiology, natural history and current practices in panic disorder with and without agoraphobia?
- What are the short-term and long-term effects of acute and extended treatment of this disorder?
- What are the short-term and long-term effects of these treatments? How should these be managed?
- What are the considerations for treatment planning?
- What are the significant questions for future research?

On the third day of the conference, following deliberation of new findings or evidence that might have been presented during the meeting, the panel will present its final consensus statement.

Information on the program may be obtained from: Carol Sadler, Prospect Associates, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852, 301-468-6338.

Dated: August 5, 1991.

Bernadine P. Healy,

Director.

[FR Doc. 91-19084 Filed 8-9-91; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Receipt of Conveyance of Mineral Interest Application

ACTION: Notice of Receipt of Conveyance of Mineral Interest Application AZA-25276.

Notice is hereby given that pursuant to section 209 of the Act of October 21, 1976, 90 Stat. 2757, Douglas Land Corporation has applied for conveyance of the federal mineral estate described as follows:

Gila and Salt River Meridian

Parcel 1

T.4N., R.4W.,
Sec. 7, lots 1 thru 4, inclusive, E½W½, E½;
Sec. 18, lots 1 thru 4, inclusive, E½W½, E½E½;
T.3N., R.5W.,
Sec. 3, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 4, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 5, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 6, lots 1 thru 7, inclusive, SE¼NW¼, S½NE¼, E½SW¼, SE¼;
Sec. 7, lots 1 thru 4, inclusive, E½W½, E½;
Sec. 8, all, except CAP portion;
Sec. 9, all, except CAP portion;
Sec. 10, all;
Sec. 11, W½;
Sec. 14, W½;
Sec. 15, all;
Sec. 23, E½NE¼, W½NW¼.
T.4N., R.5W.,
Sec. 1, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 3, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 4, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 5, lots 1 thru 4, inclusive, S½N½, S½;
Sec. 6, lots 1 thru 7, inclusive, S½NE¼, SE¼NW¼, E½SW¼, SE¼;
Sec. 7, lots 1 thru 4, inclusive, E½W½, E½;
Sec. 8, all;
Sec. 9, all;
Sec. 10, all;
Sec. 11, all;
Sec. 12, all;
Sec. 13, all;
Sec. 14, all;